REMARKS

Claims 1-5 and 25-45 are pending in the application. Claims 32-38 stand rejected and claims 1-5, 25-31 and 39-45 have been canceled without prejudice as being withdrawn from consideration.

By the above amendment, claims 32 and 34-36 have been amended and claims 33 and 37-38 have been canceled without prejudice. New claims 46 and 47 have been added, but the additional claims do not introduce new matter or subject matter outside the scope of the restriction requirement. The Examiner's reconsideration of the claim rejections and objections is respectfully requested in view of the above amendments and the following remarks.

Formal Matters

Applicant has amended to the title in a manner that is indicative of the claimed subject matter. Moreover, claim 36 has been amended to include a period.

Claim Rejections - 35 U.S.C. § 101

Claims 32-38 stand rejected under 35 U.S.C. § 101 for the reasons set forth on page 3 of the Office Action. Although Applicant respectfully disagrees with the claim characterizations and the basis of the claim rejections as set forth in the Office Action, the claims have been amended to include "diagnostic methods" using stool compounds as biomarkers, as opposed to claiming "biomarkers" per se. Accordingly, withdrawal of the claim rejections under 35 U.S.C. § 101 is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claims 32-38 stand rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth on pages 3-4 of the Office Action. Applicant respectfully disagrees with Examiner's contention that the present specification does not support the use of biological markers in stool for the purpose of diagnosing PDD. In contrast, Applicant's specification is replete with disclosure that would be readily recognized by one of ordinary skill in the art as being enabling for a diagnostic method of using stool markers for diagnosing PDD.

For example, the Examiner is respectfully directed to Page 10, line 17, through Page 11, line 5, wherein Applicant discloses that:

> Tests were performed to measure the fecal chymotrypsin levels (referred to herein as Fecal Chymotrypsin Test) in children who span the entire PDD spectrum and whose symptomotology place them in this DSM IV category. As demonstrated below, such tests revealed that a majority of the children diagnosed with autism, ADD and ADHD, for example, had abnormal chymotrypsin levels. It is believed that such abnormal levels of chymotrypsin have not heretofore been identified in the PDD population of children and adults.

Moreover, the above statement is clearly supported by data illustrated in FIGs. 13, 15 and 16, for example, regarding fecal chymotrypsin levels of individuals diagnosed as having Autism, ADHD and ADD. Thus, based on the above disclosure and other teachings of Applicant's specification, one of ordinary skill in the art would readily recognize that Applicant's specification provides adequate support for claims directed to methods for using stool compounds, such as fecal chymotrypsin, which are indicative of insufficient protein digestion or pancreatic dysfunction, as biomarkers for determining if a person has PDD.

Moreover, Applicant respectfully disagrees with Examiner's conclusion that "undue experimentation" would be required to determine or otherwise practice, the use of a stool compound as a biomarker for diagnosing PDD. To begin, Applicant's specification clearly provides specific data and working examples with respect to fecal chymotrypsin. Given that abnormal levels of fecal chymotrypsin are not found in normal individuals, Applicant's data showing that the presence of low levels of chymotrypsin in stool is commonly found in the stools of individuals diagnosed with PDD is a clear indication to one of ordinary skill in the art that chymotrypsin can be used as a biomarker for diagnosing whether a person has PDD or not.

Further, Applicant's specification teaches and suggests to one of ordinary skill in the art that stool compounds which are indicative of insufficient protein digestion or pancreatic insufficiency can be used as biological markers for diagnosing PDD. Although Applicant's specification arguably does not specifically provide working examples with respect to specific compounds other than chymotrypsin, there is no basis for "non-enablement" with respect to the claimed methods of using stool compounds as biomarkers for diagnosing PPD.

Indeed, as acknowledged by the Examiner, methods for analyzing stool compounds such as fecal chymotrypsin, and other compounds indicative of pancreatic dysfunction, for example, are extremely well-known in the art. Moreover, methods for diagnosing various PDDs (based on behavior and/or symptoms, e.g., CARS for Autism) are also extremely and notoriously well-known in the art. Because the tools for one of ordinary skill in the art to practice Applicant's invention are readily available and well-known, there is no basis for "non-enablement" of the claimed inventions.

More specifically, to practice the claimed inventions, one of ordinary skill in the art can use one or more of the well-known methods for diagnosing PDD to identify individuals having PDD. Then, one of ordinary skill in the art can use one or more well-known methods for analyzing the stools of the PDD individuals to identify stool compounds that indicate insufficient protein digestion or pancreatic dysfunction, as possible biomarkers. Thereafter, one of ordinary skill in the art could readily identify a stool compound as being a biomarker if the presence of the stool compound (e.g., one that indicates insufficient protein digestion or pancreatic dysfunction, for example) is commonly found in the PDD individuals with some statistical significance. Notwithstanding that *some* experimentation may *possibly* be needed by one of ordinary skill in the art to practice the claimed inventions, given that various methods for diagnosing PDD and analyzing stools are extremely and notoriously well known, it is respectfully submitted that there is no basis for concluding that such experimentation would be "undue".

Accordingly, for at least the above reasons, the claimed inventions are clearly enabled by Applicant's specification. Therefore, withdrawal of the rejections under 35 U.S.C. 112, first paragraph, is respectfully requested.

Claim Rejections - 35 U.S.C. § 112, second paragraph

Claim 37 stands rejected under 35 U.S.C. § 112, second paragraph, for the reasons set forth on pages 4-5 of the Office Action. Although Applicant respectfully disagrees with the rejection, claim 37 has been canceled without prejudice, so the rejection is moot.

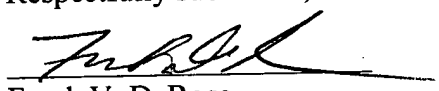
Claim Rejections - 35 U.S.C. § 102

Claims 32-38 stand rejected under 35 U.S.C. § 102 for the reasons set forth on pages 5-6 of the Office Action. Applicant believes that the claim rejections are moot in view of the claim amendments.

In any event, the basis for the rejections are unclear given Examiner's admission and acknowledgment on page 4 of the Office Action that "Examiner is not able to find established art that applies a biological marker in a stool for diagnosing a PDD." Dockter's teaching of FCT as a biomarker for determining exocrine pancreatic insufficiency provides no legal basis, whatsoever, for anticipating the present claims for using stool compounds as biological markers for diagnosing PDD. Accordingly, withdrawal of the anticipation rejections is respectfully requested.

Early and favorable consideration by the Examiner is respectfully urged. Should the Examiner believe that a telephone or personal interview may facilitate resolution of any remaining matters, it is requested that the Examiner contact Applicant's undersigned attorney.

Respectfully submitted,



Frank V. DeRosa
Reg. No. 43,584
Attorney for Applicant

F. CHAU & ASSOCIATES, LLC
1900 Hempstead Turnpike, Suite 501
East Meadow, New York 11554
Tel: (516) 357-0091
Fax: (516) 357-0092